

Notice of Allowability

Application No.

10/043,432

Applicant(s)

LE ET AL.

Examiner

Art Unit

Phillip Gambel

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/17/06; 6/2/06; 6/22/06; 8/23/06; 9/26/06; 11/7/06.
2. ☐ The allowed claim(s) is/are 1, 2, 4-11, 14, 15, 17-19 renumbered 1-15.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED ACTION

1. Given the Panel Decision from Pre-Appeal Brief Review, mailed 6/1/06, applicant's previous After Final Amendment, filed 3/17/06, has been entered.

Applicant's After Final Amendment, filed 3/17/06, has been entered.

Claims 3 and 16 have been canceled.

Claims 12-13 have been canceled previously.

Claims 1, 4, 5 and 11 have been amended

Claims 1, 2, 4-11, 14, 15 and 17-20 are pending.

EXAMINER'S AMENDMENT

3. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.
4. Authorization for this Examiner's Amendment was given in a telephone interview with Deidre Sanders on 11/7/2006.
5. Claim 20 has been canceled.
6. Extensions of time under 37 C.F.R. 1.136(a) were required in order to file the Terminal Disclaimers and to make an Examiner's amendment which places this application in condition for allowance.

During telephone conversations conducted on 8/23/06 and 11/7/06, Deirdre Sanders requested extensions of time for two (2) and three (3) months and authorized the Commissioner to charge Deposit Account No. 08/0380 the required fees of \$450 and \$1,020 for these extensions and authorized the following Examiner's Amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, It MUST be submitted no later than the payment of the Issue Fee.

REASONS FOR ALLOWANCE

7. The following is an Examiner's Statement of Reasons for Allowance:

Applicant's amendments, filed 4/17/06 and 6/15/06, including the terminal disclaimer, filed 6/15/06, have obviated the previous rejections of record. The instant methods of treating rheumatoid arthritis with A2-specific TNF α -specific antibodies appear to be free of the prior art. Accordingly the instant claims are deemed allowable.

The terminal disclaimers (including copies of the terminal disclaimers) filed on 6/2/06; 6/22/06; 8/23/06 and 9/26/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of USSNs 10/010,229 and 10/957,134 as well as U.S. Patent No. 5,919,452 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Applicant's amendments, in conjunction with the Townsend 132 Declaration, filed 3/17/06, has satisfied the requirements under 35 U.S.C. § 112, first paragraph, for the deposit of biological materials, namely the A2 antibody produced by the hybridoma ATCC Accession No. PTA-7045.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

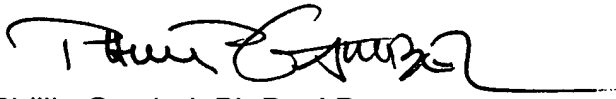
The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Phillip Gambel", with a long horizontal flourish extending to the right.

Phillip Gambel, Ph.D., J.D.

Primary Examiner

Technology Center 1600

November 13, 2006